

OCT 8 1997

Burnishine Products
Division of the Herbert Stanley Company
1100 Lakeside Drive
Gurnee, IL 60031

Attention: Dr. Kyle Sibinovic, Agent

Subject: Burnishine Germicidal Solution
File Symbol No. 1130-15
Amendments Dated July 28, and August 6, 1997

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for State registration purposes, is acceptable subject to the comments listed below.

1. Revise the statement "For use in dairies, food processing plants, food establishments, restaurants, taverns and commercial kitchens (disinfected food contact surfaces must be rinsed with potable water before reuse" to "For use as a disinfectant in dairies, food processing plants, food establishments, restaurants, taverns and commercial kitchens (disinfected food contact surfaces must be rinsed with potable water before reuse"
2. For the storage and disposal section, the instructions for disposal of unused product states that it can be poured down the drain, followed by large quantities of water. The labeling is inconsistent with PR Notice 83-3 Section (B)(2). Please refer to PR Notice 83-3, Section (B)(2) for the appropriate wording for disposal of unused products.
3. The revised Confidential Statement of Formula dated July 24, 1997 to add a new perfume is not acceptable. Ask your supplier to submit to the Agency the complete composition for perfume "Natural Lemon Flavor #203L" including the chemical name, CAS Reg. No., and percentage of each component in the fragrance mixture.

CONCURRENCES

SYMBOL	7570W						
SURNAME	M. Terry						
DATE	10/8/97						

295

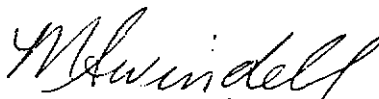
-2-

4. The revised CSF is not acceptable until the above information has been submitted and reviewed.

A stamped copy of the labeling is enclosed for your records. Submit two (2) copies of final printed label before you release the product for shipment.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell
Acting Product Manager (33)
Regulatory Management Branch I
Antimicrobial Division (7510W)

Enclosure

395

Master Label

Front Copy

ACCEPTED
with COMMENTS
in EPA Letter Dated:

BURNISHINE GERMICIDAL SOLUTION

OCT 8 1997

**One Step Cleaner
& Disinfectant, Sanitizer (Non-Food Contact Surfaces) and
Deodorizer for Disinfecting Contaminated Surfaces**

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

1130-15

ACTIVE INGREDIENTS

n-Alkyl (68% C ₁₂ , 32% C ₁₄)	
dimethyl ethylbenzyl ammonium chloride	0.154%
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chloride	0.154%
Isopropanol	21.000%
INERT INGREDIENTS	78.692%

Keep Out of Reach of Children

CAUTION

See additional precautionary statements on back panel

For use in: CRITICAL CARE AREAS

A general purpose disinfectant where control of the hazards of cross-contamination is of prime importance. Effective in 10 minutes against a wide range of bacteria including *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa* and *Klebsiella pneumoniae*. A novel way to effectively disinfect environmental surfaces. Aids in the reduction of cross-contamination.

Exhibits effective virucidal activity; kills Influenza A2/HK (representative of the common Flu virus) and Herpes Simplex II (causative agent of genital herpes) in 30 seconds. Kills Polio I Virus in 3 minutes. Kills HIV-1 (AIDS Virus) in 30 seconds at 20-25°C. Kills Rhinovirus in 3 minutes.

Kills Canine Distemper, Pseudorabies Virus, Vaccinia Virus and Adeno Virus Type 5 in 10 minutes.

Kills *Mycobacterium bovis* BCG (Tuberculosis) in 6 minutes at 20°C.

Kills *Trichophyton mentagrophytes*, *Aspergillus niger* and *Candida albicans* in 5 minutes at 20°C. Kills pathogenic fungi in 5 minutes at 20°C.

Bactericidal, Tuberculocidal, Fungicidal and Virucidal.

Kills HIV-1 (AIDS Virus) on pre-cleaned environmental surfaces or objects previously soiled with blood or body fluids in 30 seconds at room temperature (20-25°C) in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of the human immunodeficiency virus Type 1 (HIV-1) associated with AIDS.

NET CONTENTS

Back Panel

This product kills in 10 minutes a wide range of organisms which cause such diseases as boils, eye and skin infections and food poisoning, including gram negative and gram positive bacteria such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Klebsiella pneumoniae* and *Salmonella choleraesuis* on hard, non-porous surfaces.

Exhibits effective virucidal activity against Influenza A2/HK (representative of the common Flu-virus) and Herpes Simplex Type II (causative agent of genital herpes) in 30 seconds. Kills Polio I Virus in 3 minutes. Kills *Mycobacterium bovis* BCG (Tuberculosis) in 6 minutes at 20°C.

A novel way to effectively clean, deodorize and sanitize against odor-causing organisms and disinfect hard surfaces. Aids in reducing cross-contamination. Kills dangerous germs such as *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Klebsiella pneumoniae* in 10 minutes. Kills dangerous viruses such as Influenza A2/HK and Herpes Simplex Type II in 30 seconds. Kills *Mycobacterium bovis* BCG (Tuberculosis) in 6 minutes at 20°C. Kills Polio I Virus and Rhinovirus (associated with common colds) in 3 minutes. Kills HIV-1 (AIDS Virus) in 30 seconds at 20-25°C. Easy to use. Disposable. For the reasonable person who wants to be sure. For use in public toilets, laundromats, sick rooms, hospitals, camp sites, RV's, motels, factories and offices - whenever sanitation is of prime importance.

For use in hospitals and other critical care areas where control of the hazards of cross-contamination is required. Use on surfaces and equipment surfaces such as tables, carts, baskets, counters, cabinets, and telephones in operating rooms, intensive care and emergency units. Use on stainless steel, Formica, glass and other hard, non-porous surfaces.

For use in households; in hospitals - veterinary clinics; in laundromats in washers and dryers; on folding tables; on toilet seats and bathroom fixtures; hampers and bedpans; sickrooms; offices; on telephones; and hard hats and headphones. For use in dairies, food processing plants, food establishments, restaurants, taverns and commercial kitchens (disinfected food contact surfaces must be rinsed with potable water before reuse); in hotels, in public restroom accommodations and commercial laundries; on stainless steel, chrome, porcelain, glass, Formica, vinyl, plastic and other hard, non-porous surfaces of respirators and respirator facepieces and CPR training mannequins.

Some areas of use: Hard surfaces in: Surgery, Recovery, Anesthesia, X-Ray Cat. Lab, E.R., Orthopedics, Newborn Nursery, Respiratory Therapy, Radiology, Central Supply.

DIRECTIONS FOR USE TO DISINFECT NON-FOOD CONTACT SURFACES

It is a violation of Federal law to use this in a manner inconsistent with its labeling.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Remove gross filth. Use solution as is. Do not dilute. Apply solution to thoroughly wet surface. Allow to remain wet for 10 minutes, let air or wipe dry.

FOR SURGICAL INSTRUMENT PRESOAK

Remove gross filth. Presoak surgical instruments in undiluted solution for 10 minutes or more. Proceed with normal decontamination procedure.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

OCT 8 1997

Under the Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

1130-15

Back Panel (Cont'd)

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 8 1997

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

1130-15

PERSONAL PROTECTION: When using the germicidal solution, wear disposable latex gloves, protective gown, face masks or eye coverings as appropriate when handling HIV-1 infected blood or body fluids.

CLEANING PROCEDURE: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the germicidal solution.

CONTACT TIME: Thoroughly wet surface. Allow to remain wet 30 seconds, let air dry.

Although efficacy at a 30 second contact time has been shown to be adequate against HIV-1 (AIDS virus) this contact time would not be sufficient for other organisms. Use a 10 minute contact time for disinfection against all of the organisms claimed.

DISPOSAL OF INFECTIOUS MATERIALS: Dispose of used solution in accordance with local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS Hazards to humans and domestic animals

CAUTION Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling.

STATEMENT OF PRACTICAL TREATMENT If on skin: Wash with plenty of soap and water.
If in eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

STORAGE AND DISPOSAL

PESTICIDE DISPOSAL

Unused product may be discarded by pouring down drain and flushing with large quantities of water.

CONTAINER DISPOSAL

Rinse empty container thoroughly and discard in trash. Do not reuse empty container.

**PHYSICAL OR CHEMICAL
HAZARDS**

Do not use or store near heat or open flame.

BURNISHINE PRODUCTS

Div of The HERBERT STANLEY COMPANY - GURNEE, ILLINOIS 60031